FLAVORCHEM INT. INC. – NAQADA PACIFIC
PETITON TO USDA INCLUSION OF
CARAMEL COLOR
IN NOP NATIONAL LIST

DATE SUBMITTED:

Submitted in duplicate to:
National Organic Standards Board,
c/o Robert Pooler, Agricultural Marketing Specialist,
USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456,
Washington, D.C. 20090-6456.
Phone: 202/720-3252. Fax: 202/205-7808.
e-mail: nlpetition@usda.gov.

What Are the Substances for Which a Petition May be Submitted?

Only single substances or ingredients may be petitioned for evaluation. Formulated products cannot appear on the National List. Substances that appear on USDA's current Proposed National List, 65 Fed. Reg.13626-13628 (2000), should not be petitioned for inclusion on the National List.

ALL GUIDING DOCUMENTS AVAILABLE AT:
HTTP://WWW.AMS.USDA.GOV/NOP/PETITION/PETITIONHOME.HTML

1	Petition Category	Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or made with organic (specified ingredients).
2	Substance common name:	Caramel Color
3	Manufacturer's name, address and telephone number:	D.D. Williamson Food Ingredients 1901 Payne Street, Louisville, Kentucky 40206 1-800-227-2635
4	Intended or current use of substance:	Used for Color.
5	List the "mode of action" of the substance:	
6	Substance source:	Edible Carbohydrate which are glucose, invert sugar, malt syrup, molasses, sucrose and starch hydrolysates and fractions there of. Corn Starch Hydrolysate, that is, corn syrup of high dextrose equivalent is employed most frequently by the caramel colour industry.
7	Substance processing procedure from basic component(s) to final product:*	Caramel Color is generally made batchwise in stainless steel reactors equipped with an agitator, heating and cooling coils or jackets of size to contain several thousand gallons of liquid sugar. (Certain acids, alkalis and salts as provided by the standard of Identity may be used as catalysts in amounts consistent with good manufacturing practices to assist caramelization.) Some types of caramel color are best made in open or atmospheric kettles while other types require closed pressure reactors, capable of up to 70 psi gauge

Nov. 25. 2005 1:29PM No. 7070 P. 2/33

		pressure with temperatures up to 320°F. In a typical batch, the required amount of sugar is introduced into the reactor, and warmed to facilitate mixing with liquid catalyst. The vessel is then closed and the reaction proceeds for several hours under controlled temperatures and pressure conditions. When the desired color intensity is reached, the batch is cooled, filtered and pumped into storage.
8	Summary of available previous reviews by State or private certification programs or other:	The ingredients or raw materials which may be used in the preparation of caramel color in the United States are listed in the Standard of identity for Caramel (CFR 21, 73.85)
9	Information re EPA, FDA and State regulatory authority registrations including reg numbers:	CFR 21, 73.85 Food Additive E 150c FCC (current edition)
10	Chemical abstract Service (CAS) number or other numbers:	CAS Number: 8028-89-5
11	Substance's physical properties and chemical mode of action; (a) chemical interaction (b) toxicity and environmental persistence (c) impacts of manufacture	(a) (b) Acute toxicity. It is a biodegradable product. (c)
12	MSDS sheet:	See Attached
13	National Institute of Environmental Health Studies.	N/A
14	Comprehensive substance research reviews and bibliographies including contrasting positions:	N/A
15	Petition Justification Statement:	Color of food or beverage is one of the first attributes recognized by the senses of the purchaser and consumer of the product. Caramel Color is found in soft drinks, alcoholic beverage, food products (eg. soy sauce, chocolate milk, sausage castings, soups, gravies…etc.)

Nov. 25. 2005 1:29PM No. 7070 P. 3/33

Evaluation Criteria for Substances added to the National List

Category 1. Adverse impacts on humans or the environment? Substance Caramel Color

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			N/A	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			N/A	
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]			N/A	
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			N/A	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			N/A	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			N/A	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			N/A	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			N/A	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			N/A	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]				Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			N/A	
12. Is the substance GRAS when used according to FDA's good				Yes. 182.1235, 582.1235, 73.1085, 73.2085,73.85

Nov. 25. 2005 1:30PM No. 7070 P. 4/33

manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			N/A	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Nov. 25. 2005 1:30PM No. 7070 P. 5/33

Category 2. Is the Substance Essential for Organic Production? Substance Caramel Color

Question	Yes	No	N/A	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]				Caramel Color is generally made batchwise in stainless steel reactors equipped with an agitator, heating and cooling coils or jackets of size to contain several thousand gallons of liquid sugar. (Certain acids, alkalis and salts as provided by the standard of Identity may be used as catalysts in amounts consistent with good manufacturing practices to assist caramelization.) Some types of caramel color are best made in open or atmospheric kettles while other types require closed pressure reactors, capable of up to 70 psi gauge pressure with temperatures up to 320°F. In a typical batch, the required amount of sugar is introduced into the reactor, and warmed to facilitate mixing with liquid catalyst. The vessel is then closed and the reaction proceeds for several hours under controlled temperatures and pressure conditions. When the desired color intensity is reached, the batch is cooled, filtered and pumped into storage.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]				Edible Carbohydrate which are glucose, invert sugar, malt syrup, molasses, sucrose and starch hydrolysates and fractions there of. Corn Starch Hydrolysate, that is, corn syrup of high dextrose equivalent is employed most frequently by the caramel color industry.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			N/A	
4. Is there a natural source of the substance? [§205.600 b.1]			N/A	
5. Is there an organic substitute? [§205.600 b.1]		X		Not at the same strength, therefore the same color will not be achieved.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			N/A	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

Nov. 25. 2005 1:30PM No. 7070 P. 6/33